

§ 520.45

21 CFR Ch. I (4–1–05 Edition)

(3) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a)(1) *Specifications.* The product contains 11.36 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600 of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in cattle*—(i) *Amount.* 4.54 milligrams per pound of body weight (10 milligrams per kilogram).

(ii) *Indications for use.* For removal and control of the following internal parasites of cattle: Adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus*, *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications.* The product contains 4.55 or 11.36 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in sheep*—(i) *Amount.* 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).

(ii) *Indications for use.* For removal and control of the following internal parasites of sheep: Adult liver flukes (*Fasciola hepatica*, *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 25115, June 13, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 65711, Dec. 21, 1994; 60 FR 55658, Nov. 2, 1995; 61 FR 4875, Feb. 9, 1996; 64 FR 1504, Jan. 11, 1999]

§ 520.45b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae

(*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations*. Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

(b) *Sponsor*. See No. 057926 in § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.36 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use*. For suppression of estrus in mares.

(iii) *Limitations*. For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days by top-dressing on a portion of each gilt's daily feed.

(ii) *Indications for use*. For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

(iii) *Limitations*. Do not use in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis). Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

[66 FR 47960, Sept. 17, 2001, as amended at 68 FR 62006, Oct. 31, 2003]

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) *Chemical name*. 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications*. Each tablet contains 0.2 milligram of the drug.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) *Specifications*. The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.